K122998

5. 510(k) SUMMARY

DATE: February 17, 2012

NOV 6 2012

OWNER:
Northstar Healthcare Holdings
70 Sir John Rogerson's Quay
Dublin 2, Ireland

OFFICIAL CORRESPONDENT:
Michael Riordan
Operations Manager
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DEVICE NAME:

Trade Name: Textured, Blue Powdered Nitrile Examination Glove

Common Name: Patient Examination Gloves

Classification: Patient Examination Gloves

Class: Class I

Product Code: LZA

PREDICATE DEVICE(S):

Predicate 510(k)	Device Name	Indication	Clearance Date	Company
K974907	Nitrile Powdered Examination Gloves	The examination glove is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	13 Mar 1998	Smart Glove Corp., SDN, BHD

DEVICE DESCRIPTION: Nitrile Powdered patient examination glove

STATEMENT OF INTENDED USE:

The Nitrile Powdered Examination Glove is a Disposable device intended for medical and dental purposes to be worn on the examiner's hand or finger to prevent contamination between patient and examiner.

TECHNOLOGICAL CHARACTERISTICS:

The Nitrile Powdered Examination Glove is substantially equivalent to the predicate device with regard to physical characteristics, design, product features, and intended use. Both gloves are made with nitrile using similar manufacturing processes.

Feature	Nitrile Powdered Examination Gloves K974907 Predicate	Textured, Blue Nitrile Powdered Examination Gloves Proposed
Intended Use	Intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	Same
Indications for Use Statement	The examination glove is a disposable device intended for medical and dental purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.	The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
Description	The powdered examination gloves made of nitrile. The gloves are provided in sizes extra small, small, medium, large and extra large.	The powdered examination gloves made of nitrile. The gloves are provided in sizes small, medium, large, and extra large.
Presentation	Gloves are provided in dispenser boxes.	Same
Material	Nitrile	Same
Sterilization	Non-sterile	Same
Single Use	Yes	Same
Dimensions	Meets ASTM D3578-95	Length: Small 230 mm min.; Medium 230 mm min.; Large 230 mm min.; Extra Large 230 mm min. Width: Small 80-90 mm; Medium 90-100 mm; Large 100-110 mm; Extra Large 110-120 mm Thickness: Finger 0.08 mm min.; Palm 0.06mm min
Physical Properties	Meets ASTM D3578-95	Before aging/after aging Elongation 500% 500% Tensile Strength 14MPa 14MPa
Freedom from Pinholes	Meets ASTM D5151-92	Meets ASTM D5151-06
Residual Powder	Meets ASTM D6124-97	Meets ASTM D6124-06

ASSESSMENT OF NONCLINICAL DATA:

Characteristic	Standard	Device Performance
Dimension	ASTM Standard D6319-10	Meets
Physical Properties	ASTM Standard D6319-10	Meets
Freedom from Pinholes	21 CFR 800.20; ASTM D5151-06	Meets
Powder Residual	ASTM Standard D6124-06	Meets Results generated values below 10 mg/dm^2 of powder
Biocompatibility	Primary Skin Irritation in rabbits (ISO 10993-10:2010)	Gloves are non-irritating
	Dermal Sensitization in the guinea pig (ISO 10993-10:2010)	Gloves do not display any potential for sensitization

CONCLUSIONS:

The Nitrile Powdered Examination Gloves meet the requirements of established standards ASTM D6319-10, ASTM D5151-06, ASTM D6124-06 and ISO 10993-10:2010.

Based on the comparison of intended use, design, materials and performance, the Nitrile Powdered Examination Gloves are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 6, 2012

Northstar Healthcare Holdings
C/O Underwriters Laboratories, Incorporated
Mr. Ned Devine
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K122998
Trade/Device Name: Textured Blue Powdered Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: October 19, 2012
Received: October 22, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Anthony D. Watson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.06 14:26:52 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122998

Device Name: Textured Blue Powdered Nitrile Examination Glove

Indications for Use: The examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

AND/OR

Prescription Use_____
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___X___
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for ECW

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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